REMARKS/ARGUMENTS

The Examiner objected to claims 27 and 28 as being dependent upon a rejected base claim, but indicated that the claims would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

Claim 27 has been rewritten in independent form. In doing so the potentially indefinite term "preferably" has been deleted from the claim. New claim 29 has been added dependent on claim 27, directed to the preferred concentration range previously recited in claim 27. Claim 28 is dependent on claim 27. Having regard thereto, it is submitted that claims 27 to 29 are in an allowable form.

The Examiner rejected claims 1 to 28 under the judicially-created doctrine of obviousness type double patenting as being unpatentable over claims 1 to 27 of US Patent No. 7,645,468.

A rejection of obviousness-type double patenting may be overcome by the filing of a Terminal Disclaimer, which may be signed by an attorney or agent of record. Submitted herewith is a Terminal Disclaimer, disclaiming the term of the patent to be granted on this application which may extend beyond the term of US Patent No. 7,645,468, signed by an agent of record. Authorization to charge the prescribed recordal fee to our deposit account is included herewith.

Having regard thereto, it is submitted that the claims of this application can no longer be considered to be unpatentable over claims 1 to 27 of US Patent No. 7,645,468 and hence the rejection of obviousness-type double patenting should be withdrawn.

The Examiner rejected claim 1 under 35 USC 102(e) as being anticipated by Higgs et al (US 6,955,831).

Claim 1 has been amended in several respects to a form which, it is submitted, can no longer be considered to be anticipated by Higgs et al. Claim 1 has been amended to recite that it is directed to the production of a canola protein isolate. Higgs et al is concerned solely with the provision of a concentrate. The rejection based on Higgs et al did not include claim 7. Claim 1 also has been amended to recite that the heat treatment is effected on intact canola seeds and the conditions of the heat treatment, as specified on page 4, paragraph [0019]. In addition, the subject matter of claim 7, reciting that the canola oil seed meal is processed to recover therefrom the canola protein isolate, has been incorporated into claim 1.

Accordingly, it is submitted that claim 1, in its amended form, can no longer be considered to be anticipated by Higgs et al and hence the rejection thereof under 35 USC 102(e) as being anticipated by Higgs et al, should be withdrawn.

The Examiner rejected claims 1 to 10 as being unpatentable over Higgs et al (US 6,955,831) in view of Cisneros et al (US 6,808,621).

First of all, it should be recognized that the Higgs reference relates to a method of making a concentrate and not an isolate. The present claims are directed to the production of an isolate which, by definition, must contain a protein content of at least about 90 wt% (N x 6.25). A "concentrate" contains less protein. There is no suggestion in Higgs to obtain an isolate. The reference describes heat treatment of oil seeds. For example, in col. 3, ll 48 to 51, it is stated:

> "subjecting said oilseed to heat treatment to substantially reduce the concentration of at least some antinutritional components normally present in said oilseed to obtain heat-treated seed"

However, the only heat treatment specifically identified is a two-step heating operation which:

> ".....is a rapid heat treatment. The heat treatment may be carried out in one or more stages, for example, a two stage

> heat treatment can be employed where temperatures range from about 100°C to 115°C, and for treatment times ranging from 1.5 minutes to 30 minutes or more depending on the specific components being treated" (see col. 5, ll 25 to 31).

In addition, in Example 3, in col. 11, it is recited:

> "In a preferred embodiment of the invention, specially for canola, soya, flax and hemp, an initial heat treatment was performed. The process involved subjecting the whole seeds to infrared energy so that the seed temperature reached 110-115°C for 90 seconds. Subsequently, the micronized seeds were held for 20-30 min, depending upon the seed source, in an insulated tank where temperatures ranged from 100-110°C (residual cooking conditions). These conditions inactivated enzymes such as myrosinase in canola and trypsin inhibitors in soya as well as peroxidase and cyanogenic glucosides. Further, they ensured devitalization of viable germ tissue in hemp, improved starch digestibility, and destroyed or reduced the concentrations of heat labile antinutritional factors other than those mentioned above.

Again a two stage heating operation is described and the result is a concentrate. No attempt is made to produce a canola protein isolate. Not only does the reference not attempt to obtain a canola protein isolate, but the harsh heat treatment described would result in a product from which protein could not be extracted under mild conditions, such as specified in claims 11 to 29.

The Examiner uses the Cisneros reference apparently to show that seeds are flaked to facilitate oil removal, pointing to col. 28, ll 22 to 37. The applicants agree that flaking is a common step in oil removal from oil seeds. However, such disclosure does not make up for the other deficiencies of Higgs as pointed out above.

Accordingly, it is submitted that the amended claims are patentable over the applied prior art and hence the rejection of claims 1 to 10, insofar as they remain in the specification and in their amended form, under 35 USC 103(a) as being unpatentable over Higgs et al in view of Cisneros, should be withdrawn.

The Examiner rejected claims 1 to 26 under 35 USC 103(a) as being unpatentable over Higgs et al in view of Murray (US 6,005,076), Murray (US 5,844,086), Cisneros (US 6,808,621), Jones (US 4,158,656) and Carey (US 3,966,702).

Applicant claims (claim 1) a method of forming a canola protein isolate having a protein content of at least about 90 wt% from intact canola seeds by a plurality of steps. Such steps comprise heat treating the intact canola seeds to deactivate enzymes therein, dehulling the canola seeds, removing canola oil from the heat-treated and dehulled oil seeds to provide a canola oil seed meal and processing the canola oil seed to recover therefrom flax canola protein isolate. Claim 1 has been amended to recite heat treatment at approximately 90°C for about 5 to about 10 minutes, as recited in paragraph [0019] on page 4.

The Higgs et al reference does not produce a canola protein isolate having a protein content of at least about 90 wt% (N x 6.25) (preferably at least about 100 wt% (N x 6.25) - claim 8), from intact canola seeds. At best, Higgs et al describes the preparation of canola products which are concentrates and that do not contain at least about 90 wt% protein. The products of Higgs et al are described as "nutritionally upgraded oil seed meals which are protein and lipid-rich and have reduced fiber content" (see Abstract).

The Higgs et al procedure, as described in the Abstract, involves subjecting the oil seed (which may be canola oil seeds, col. 5, line 34) to heat treatment "to substantially reduce the concentration of at least some antinutritional components normally present in the oil seed" (see Abstract), dehulling the heat-treated product to produce a meat fraction, a hull fraction and a mixture thereof, and cold pressing the meat fraction or the mixture to yield the plant oils and the protein and lipid-rich meals, which are the product of the process (see Abstract). The process of Higgs is illustrated schematically in Figures 1 and 2.

In discussing the heat treatment step, certain criteria for that step are specified in Higgs, as in column 9, lines 21 to 27, as follows:

> "The temperature and length of the treatment is selected to substantially: (i) deactivate or destroy the activity of enzymes such as myrosinase, which is the enzyme responsible for glucosinolate hydrolysis in canola; (ii) improve the digestibility or bioavailability of the carbohydrates present in canola and other oilseeds; and (iii) reduce the moisture content in the seed, which results in a partial separation of the meat from the fibrous indigestible hull."

Thus, the temperature and method selected for the heat treatment must meet these three criteria. Applicants process requires only inactivation of enzymes as recited in claim 1, utilizing the specific conditions specified.

The Higgs reference refers to specific temperatures and times of the heating step. In column 5, lines 26 to 31, it is specified:

> "In another preferred embodiment, in any of the above process aspects, desirably the heat treatment is a rapid heat treatment. The heat treatment may be carried out in one or more stages – for example, a two stage heat treatment can be employed where temperatures range from about 100°C to 115°C and for treatment times ranging from 1.5 minutes to 30 minutes or more depending on the specific components being treated."

In column 9, lines 15 to 20, it is specified:

> "If the latter option is selected, one procedure involves heating the seed at 110-115°C for 90 seconds followed by an additional heating at 100-110°C for 30 minutes. Other options require less heat depending upon the form of heat and whether or not a vacuum is applied during the heat process."

It is clear from these passages that temperatures of 100° to 115°C are combined with heat treatment times of from 1.5 to 30 minutes. As specified in amended claim 1, Applicants heating conditions are much milder, being from 5 to about 10 minutes at approximately 90°C, as specified in paragraph [0019] on page 4 of the disclosure.

Applicants heating conditions are intended to deactivate enzymes in intact canola oil seeds. Since Applicants aim is to process the canola oil seeds to a form which permits extraction of the canola oil seed meal and the isolation of a canola protein isolate from the extracted material, the heating operation should not substantially impair the extractability of the protein from the canola oil seed meal.

Higgs et al have no such restriction. As specified in col. 9 quoted above, the heat treatment in Higgs et al is intended to accomplish three results and the heat-treated product is then processed to produce the product using the steps specified above. The treatment of the oil seed at 100° to 110°C for 30 minutes, as specified in col. 9, would lead to impairment of the extractability of the protein from the heat treated product. This result is of no concern to Higgs et al, since he does not propose to process the protein concentrate further. In contrast, it is of significance to the invention that the protein in the canola oil seed meal be extractable so that the canola protein isolate can be recovered as the product of the process.

In addition to this distinction from Higgs, the Examiner concedes in the Office Action, that the Higgs et all reference lacks an express teaching of features of the applicants claim 1, as follows:

> "Higgs, however, does not expressly teach within its preparation steps the claimed specific temperature and time to heat the canola seeds oil to deactivate enzymes therein [the specific temperature and time was not specified in claim 1, but now is], cooling the heated canola seeds [claim 3] and/or wherein said heat treated and dehulled oil seeds are flaked prior to said oil removal step [claim 2] and/or the canola oil seed meal is processed to recover therefrom a canola protein isolate having a claimed protein content [not specified in claim 1] by the steps of extracting the canola oil seed meal to cause solubilization (i.e. solubilization is done with a particular concentration of oil seed meal in the aqueous food grade salt, with a particular solvent such as a food grade salt of sodium chloride and/or using water extraction subsequent to using the food grade product, agitation of the food grade salt for a particular time range and solubilization is also done at a particular temperature and pH) and then continuously conveying said mixture through a pipe while

> extracting protein from the oil seed meal to form a particular range concentration of an aqueous protein solution, separating the aqueous protein solution from residual canola oils seed meal, after separating conducting a pigment removal step whereas pigment absorbing agent to be mixed with the aqueous protein solution to prepare a protein isolate of reduced pigment and/or performed by diafiltration (i.e. an anti-oxidant is present in the diafiltration step) of the aqueous protein solution, increasing the protein concentration of an aqueous protein solution by ultrafiltration and/or diafiltration at a particular temperature to produce a particular range concentrated protein solution, diluting the concentrated protein solution with chilled water at a particular temperature to cause formation of protein micelles, settling the protein micelles to form a protein micellar mass and recovering the protein micellar mass from the supernatant. [Claims 11 to 25]." (Insertions added).

The Examiner attempts to remedy these defects with reference to the Murray references, the Cisneros reference, the Jones reference and the Carey reference. The Murray references are relied on by the Examiner for the same teachings and, hence, need not be considered separately. The Murray references appear to be relied on solely with respect to the subject matter of claims 1 and 11 to 25.

It is agreed with the Examiner that the Murray references disclose a process of preparing an oil seed protein isolate having a protein content of at least about 90 wt% (N x 6.25) from oil seed meal and that the oil seed meal may be canola oil seed meal, as specified in claim 1.

It is further agreed with the Examiner that the Murray references generally describe the combination of process steps specified in claim 11, except for concentration of the canola protein solution to a concentration of at least about 200g/L, preferably at least about 250 g/L. However, Murray et al is silent as to the treatment of canola oil seeds by a procedure as defined in claims 1 to 4. In addition, given the teachings of Higgs et al as to the production of a concentrate, there would be no reason for a person skilled in the art to use the product of Higgs et al as a starting material for the Murray procedure.

It is noted that the Higgs reference specifically refers to the Murray patents in col. 2, lines 48 to 56. The passage recites that the Murray references produce a protein isolate and specifically states:

> "which is regarded as being different from a protein concentrate."

which is the product of the Higgs procedure. The passage further states:

> "...the process of the preparation of an isolate does not allow for a heating step at elevated temperature."

Thus, the Higgs reference specifically contrasts the Murray process and states that, in the preparation of an isolate, as in the claims of this application, it is not possible to include a heating step at elevated temperature. Yet, in the present invention, there is an initial heat treatment step and an isolate is provided.

With respect to the subclaims 12 to 25, the Murray references do not disclose the features specified in:

- Subclaim 14 with respect to a combination of process conditions for a continuous process
- Subclaim 17 with respect to effecting a pigment removal step on the aqueous canola protein isolate separated from the residual canola seed meal
- Subclaim 17 with respect to effecting the pigment removal step by diafiltration
- Subclaim 17 with respect to effecting the pigment removal step by mixing a pigment adsorbing agent with the aqueous protein solution and subsequently removing the pigment adsorbing agent from the aqueous protein solution
- Subclaim 18 with respect to extracting the canola oil seed meal with water and subsequently adding salt thereto to provide an aqueous protein solution having an ionic strength of at least about 0.10

- Subclaims 20 and 21 with respect to subjecting the concentrated protein solution to a diafiltration step using an aqueous salt solution of the same molarity and pH as the extracting solution until no further quantities of phenolics and visible colour are present in the permeate in which an anti-oxidant is present during at least part of the diafiltration step
- Claim 22 with respect to subjecting the concentrated protein solution, optionally diafiltered to a pigment removal step
- Claim 23 with respect to subjecting the concentrated protein solution, optionally diafiltered, to a pasteurization step

The Examiner apparently relies on Cisneros for a teaching that seed is flaked to facilitate oil removal, referring to column 28, lines 21 to 37. As previously specified, it is agreed that flaking is a common step in oil removal from oil seeds. This reference would appear to be relied on by the Examiner solely for the features of claim 2 and, it is submitted, does not remedy the defects of the Higgs et al reference recited above, nor, it is submitted does it remedy the defects of the Murray references enumerated above.

The Jones reference is cited in the Office Action for the teaching:

> "Jones beneficially teach in order to purify and/or detoxify the canola seed meal, one can utilize an antioxidant extraction step (i.e. the anti-oxidation extraction step performed in the diafiltration step) to purify. Jones also teaches that pigment removed from the oil seed is beneficial because color is highly undesirable in many foods. (see, e.g. abstract, column 3 lines 20-27, column 4 lines 16-68, column 5 lines 1-15)",

while the Carey reference is cited in the Office Action for the teaching:

> "Carey beneficially teaches the adsorbing agents (i.e. activated carbons) are beneficial to decolorize the protein material in oil seeds when producing oil seed protein isolates (see, e.g. abstract)"

These references, therefore, are cited for relevance only to those claims relating to pigment removal steps, namely claims 17 to 22. The references are not cited for relevance to any other claim features, it would appear.

The specific process described in Jones is the processing of defatted oil seeds, including rapeseed (canola), in which dehulled, defatted seeds are extracted with an aqueous alcohol solvent under substantially non-oxidizing conditions, so as to prevent oxidation of contained phenolic compounds and inhibit enzymatic degradation of glucoinsolates, to produce a detoxified protein concentrate.

It is agreed with the Examiner that, in general, Jones et al teach the benefit of an antioxidant extraction step to purify and/or detoxify canola seed meal and that removal of pigment from oil seed is beneficial due to the undesirability of colour in many foods.

However, Jones et al is silent as to any specific procedures for carrying out the desired detoxification/pigment removal in the seed beyond aqueous alcoholic extraction under non-oxidizing conditions. The reference is simply silent as to the "diafiltration step" to which the Examiner refers in the Office Action.

Carey describe the production of protein isolates from vegetable oil seeds by extracting a ground oilseed material with an alkaline extractant to provide an alkaline protein extract with a pH of at least about 9.5, passing the alkaline extract through activated carbon to deflavorize and decolorize the protein material, followed by precipitation and isolation of the deflavorized protein (abstract).

At best, therefore, the Jones et al and Carey et al references are relevant only to claims 17 and 22. There is no disclosure in either reference of the use of a diafiltration operation effected on the aqueous canola protein isolate (claim 17) nor the concentrated protein solution (claim 17) nor the use of a pigment removal step on the concentrated protein solution (claim 22).

In the Office Action, the Examiner states:

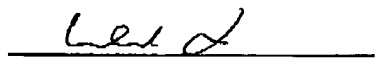
"It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Higg's method of preparing a canola protein to beneficially include the claimed preparation steps and/or teachings of both Murray's preparation steps of preparing a canola protein isolated as well Jones and Carey's preparation step of pigment removal of a canola and Cisneros's teaching of the plant seeds are flaked to facilitate oil removal within Higg's method of preparation steps because the overall above combined teachings would create the claimed invention's canola protein isolate of reduced pigment within the claimed protein content comprising the utilization of the overall combined steps of the cited references."

It is submitted that, for the reasons discussed above, and the defects of the references and their combinations, applicants method, as defined in the amended claims, is not obvious having regard to the cited prior art.

Accordingly, it is submitted that claims 1 to 26, insofar as they remain in the application and in their amended form are patentable over the applied prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Higgs et al in view of the Murray references, Cisneros, Jones and Carey, should be withdrawn.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,



Michael I. Stewart
Reg. No. 24,973

Michael I. Stewart/jb
Toronto, Ontario, Canada
PH. No.: (416) 849-8400
FAX No.: (416) 595-1163